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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,605	01/27/2004	Peter Chumakov	SBIO/0002.D1	3828

7590 01/26/2007
MOSER, PATTERSON & SHERIDAN, L.L.P.
Suite 1500
3040 Post Oak Blvd.
Houston, TX 77056

EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/766,605

Applicant(s)

CHUMAKOV ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/15/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

Serial No.: 10/766,605

Applicants: Chumakov, P., and A. Chenchik

Docket No.: SBIO/0002.D1

Filing Date: 01/27/2004

Detailed Office Action

Status of the Claims

Applicants' election of Group I (claims 1-24) in the communication dated 02 November, 2006, is acknowledged. Because applicant did not distinctly and specifically point out the purported errors in the restriction requirement, the election has been treated as an election without traverse (refer to M.P.E.P. § 818.03(a)). Claims 25-27 have been withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

37 C.F.R. § 1.98

The information disclosure statement filed 15 September, 2005, has been considered.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 10, 12, and 13 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Trono and Wiznerowicz (2003). This teaching provides a viral transcriptional reporter vector comprising a retroviral vector backbone, conditional promoter, and first reporter cassette, wherein said vector is packaged into vector particles. Thus, this teaching meets all of the claimed limitations.

Claims 1, 2, 10, and 12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nakajima et al. (2000). This teaching provides a viral transcriptional reporter vector comprising a retroviral vector backbone, conditional promoter, and first reporter cassette, wherein said vector is packaged into vector particles. Thus, this teaching meets all of the claimed limitations.

Claims 1, 2, 9, 12, and 13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Johnston et al. (2002). This teaching provides a viral transcriptional reporter vector comprising a retroviral vector backbone, conditional promoter, and first reporter cassette, wherein said vector is packaged into vector particles. Thus, this teaching meets all of the claimed limitations.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior

art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-9 and 11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Trono et al. (2003) in view of Nakajima et al. (2000). Trono and colleagues provide a viral transcriptional reporter vector comprising a retroviral vector backbone, conditional promoter, and first reporter cassette, wherein said vector is packaged into vector particles. Various promoters and reporters are also disclosed. This teaching does not disclose a second reporter cassette in the same construct. However, Nakajima and colleagues provide a retroviral construct with two reporters, albeit under the control of a single promoter. However, it would have been *prima facie* obvious at the time of the invention to prepare a retroviral transcriptional vector with a first promoter and reporter gene and a second promoter and reporter gene. One of ordinary skill in the art would have been motivated to do so since this would enable the skilled artisan to express multiple therapeutic inserts with different tissue specificities or levels of expression from the same construct.

Claims 14-20 and 22-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Trono et al. (2003) in view of Kim (2002). Trono and colleagues provide a viral transcriptional reporter vector comprising a retroviral vector backbone, conditional promoter, and first reporter cassette, wherein said vector is packaged into vector particles. Various promoters and reporters are also disclosed. This teaching does not provide a

pathway-specific response element (e.g., p53 binding sequences from p21) under the control of a conditional promoter. However, Kim provides a detailed teaching pertaining to the use of pathway-specific promoter elements (e.g., p53 binding sequences from p21) operably linked to a reporter gene. This teaching also discloses the preparation and use of double reporter constructs. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of filing to employ the pathway-specific promoter elements provided by Kim in the constructs of Trono and colleagues since this would enable one of ordinary skill in the art to regulate heterologous gene and reporter expression in a tight manner. It would have also been *prima facie* obvious at the time of the invention to prepare a retroviral transcriptional vector with a first promoter and reporter gene and a second promoter and reporter gene. One of ordinary skill in the art would have been motivated to do so since this would enable the skilled artisan to express multiple therapeutic inserts with different tissue specificities or levels of expression from the same construct.

Claim 21 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Trono et al. (2003) in view of Kim (2002), as applied *supra* to claims 14-20 and 22-24, and further in view of Johnston et al. (2002). Neither Trono et al. nor Kim disclose the preparation of FIV expression vectors. However, Johnston and colleagues provide FIV-based retroviral vector expression vectors. Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art to employ the FIV backbone of Johnston and colleagues since Trono and associates teach that this also represents a suitable expression vector.

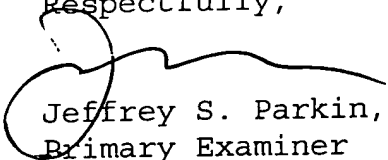
Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,


Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

21 January, 2007